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| 08/791,240 | 01/30/97 | RYNCLARZ | BDI-1020 |

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HM31/0330

EXAMINER
SISSON, B

ART UNIT
1534

PAPER NUMBER

DATE MAILED: 03/30/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/791,240

Applicant(s)

Alexander J. Ryncarz

Examiner

Bradley L. Sisson

Group Art Unit

1634



☒ Responsive to communication(s) filed on 30 Jan 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-58 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-58 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Claim Rejections - 35 USC § 112

2. Claims 1-6, 11, 27, and 39-57 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

See page 2 of the prior Office action for the basis of the rejection.

Remarks

At page 5 of the response having a Certificate of Mailing date of 30 January 1998, hereinafter the response, it is asserted that claims 1-6 and 39-57 are not indefinite as the recitation of one oligonucleotide primer does not render the claim unambiguous.

The above argument has been fully considered and has not been found persuasive because the claim is drawn to an improved method of performing nucleic acid amplification reaction. The claim sets forth that one is to use a primer for performing primer extension reactions and the target nucleic acid can also be the result of a primer extension reaction. Taking applicant's argument at face value, it would appear that the primer ("primer A") which is used to perform a primer extension reaction

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can then be used as a template, or target nucleic acid for the very same reaction when a non-extended primer (primer A) is to be used. This cannot be. A primer will hybridize to a complementary sequence (non-primer A sequence), it will not hybridize to its own sequence (primer A).

Claims 4, 11, 27, 41, and 53 remain indefinite with respect to just what constitutes "substantially." In response to the above rejection, applicant has pointed to page 26, lines 13-20, of the specification as providing a definition of the term. Upon review of said page 26, not such definition can be located. It appears that page 26, rather than providing a definition to the above rejected term, provides a listing of organisms by genus species, starting with *Haemophilus aegypticus*; this listing of organisms extends from pages 24-30. Claims 5 and 6 which depend from claim 4; claims 12 and 13 which depend from claim 11; claims 42 and 43 which depend from claim 41; and claims 54-57 which depend from claim 53 fail to overcome this issue and are similarly indefinite.

3. Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 58 is confusing with respect to the number and variety of primers. It is noted that the claim refers to "an oligonucleotide primer," yet it also states that "said primers are the same or different." If there are a plurality of primers, which are the one(s) that have the non-complementary 3'-end?

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis et al., in view of Kiessling, Davis et al., and Gillespie.

See the prior Office action at pages 3-5 for the basis of the rejection.

Remarks

At page 7 of the response, it is asserted that "the rejection represents hindsight reconstruction of the Applicant's invention and that there would be no motivation to combine the references in the way the Examiner has done." Over the following pages of the response, applicant provides an analysis of only the last two cited prior art teachings, and then in reverse order.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference or that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981), at 208 USPQ 881. This is the standard employed herein.

At page 8 of the response, it is asserted that the claimed method is "completely different" from that disclosed in the prior art and that "the primers of the present invention are essentially non-competitive." Applicant's argument has been fully considered and has not been found persuasive for applicant is arguing limitations not present in the claims. Even if the claims were to be so amended, it is noted that the use of nested PCR (Mullis et al.), does not present a competitive primer setting.

At page 8 of the response it is asserted that none of the cited prior art teaches amplifying multiple templates in the same reaction. This assertion is wholly false for as pointed to in the prior Office action (see page 3, paragraph 5) Mullis et al., teach explicitly of performing nested PCR where two different sets of primers are used to amplify two different target sequences in the same reaction. As can be seen in Fig. 10, which represents the amplification product run on a gel, both sizes of anticipated amplification product are present (58-bp and 110-bp fragments). Clearly, the teachings

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of Mullis et al., and the types of labels that can be used, speak directly to quantitative and qualitative means for detection and are in direct opposition of applicant allegations at page 9 of the response that “Applicant can find no teaching or suggestion in the cited references of Applicant’s method of providing qualitative or quantitative determination of multiple templates and of providing an indication of functional amplification conditions.”

For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained against claims 1-57 and is also applied against new claim 58.

Conclusion

6. No claim is allowed.

Rejections which appeared in the prior Office action and which were not repeated hereinabove, have been withdrawn.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be


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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978 and whose e-mail address is bradley.sisson@uspto.gov. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The fax phone numbers for Group 1630 are (703) 305-3014 and (703) 305-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.


BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP 1800-1630
3-30-98